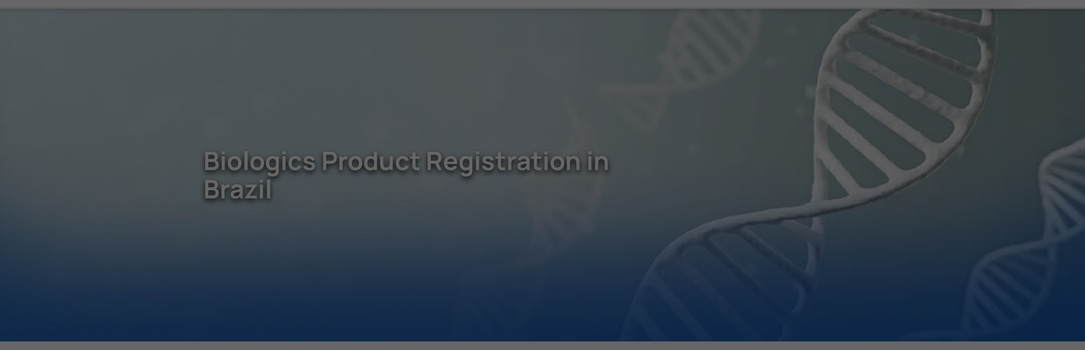

Biologics Product Registration in Brazil

Accelerate Your Biological Product Approval in Brazil with DDReg

Entering the Brazilian biopharmaceutical market requires precise regulatory strategy, technical documentation, and local insight. Biologics product registration in Brazil is governed by the Agência Nacional de Vigilância Sanitária (ANVISA), which regulates biologics, biopharmaceuticals, and biosimilars under well-defined frameworks.

At DDReg, we specialize in end-to-end biologics registration services in Brazil, offering regulatory affairs expertise, local representation, and complete lifecycle management to help global life sciences organizations achieve successful market access.

Understanding Biologics Registration in Brazil

Brazil is the largest pharmaceutical market in Latin America and has one of the most dynamic regulatory frameworks for biologics and biosimilars. The Agência Nacional de Vigilância Sanitária (ANVISA) regulates the registration of these products under Resolution RDC 55/2010, later enhanced by RDC 875/2024, which introduced new reliance and streamlined pathways for biosimilars.

Under ANVISA's biologics classification:

- A New Biological Product is an innovative biologic active substance not previously registered in Brazil.
- A Biological Product refers to a follow-on version (biosimilar) of an existing biologic registered in Brazil.

The two main regulatory pathways for biological product approval in Brazil include:

1. Comparability Pathway – requires extensive comparability data with the reference biologic.
2. Individual Development Pathway – allows reduced comparative studies when scientifically justified.

Our Regulatory Affairs Services for Biologics Products in Brazil

+ Regulatory Strategy & Classification Support
+ Dossier Compilation and Submission (CTD/eCTD)
+ GMP and Quality Compliance
+ Biosimilar & Biopharmaceutical Registration Support
+ Post-Registration and Lifecycle Management
+ Local Regulatory Representation & Communication

Why Choose DDReg for Biologics Product Registration in Brazil?

Partnering with DDReg gives your organization a regulatory advantage built on science, compliance, and local intelligence. We combine our deep technical expertise in biologics and biosimilars with over 16 years of experience in global regulatory affairs services to streamline your path to ANVISA approval.

Our team understands the complex interplay between CMC comparability, clinical bridging, and GMP certification that determines biologic product approval in Brazil. With access to regulatory intelligence and local partners in Brazil, DDReg ensures your regulatory submission strategy aligns with the latest RDC guidelines, subject codes, and procedural changes.

Country Specific Services

- Regulatory
- Pharmacovigilance
- Labeling
- IPR Support
- Clinical Trial Regulatory
- Medical Devices regulatory services

Contact DDReg today to discuss your biopharmaceutical or biosimilar product registration in Brazil.

Connect with Our Experts

Frequently Asked Questions

01 What documents are required for ANVISA Biologics Registration?

02 What is the difference between a biological and a new biological product?

03 How long does it take to register a biologic in Brazil?

04 Can a foreign company apply directly to ANVISA?

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